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Looking back and going forward: What should the new European Commission do in order to promote evidence-based policy making?

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Abstract

In this paper we first give an overview of what has happened in Europe within the area of regulation over the past 5 years or so. We then examine where the new European Commission and the Parliament are with regard to evidence-based and risk-informed policy making taking a specific look at the importance of transparency among European regulatory agencies, the calls for better regulation that were initiated by First Vice President Timmermans, and the continued miss-use of the precautionary principle. In the final section we provide a number of recommendations on what the Commission and the Parliament should do going forward including moving away from fish bowl to science based transparency, making the member states more receptive to science based policy making and strengthening the capacity of the European Commission to further promote evidence-based and risk-informed policy making.

1. Introduction

Regulation in Europe is becoming increasingly polarized. Over the past fifteen years we have seen the death of consensual style of regulation (Majone and Evans 2001) and the rise of adversarial model of regulation (eg Lofstedt 2014b). This is especially prevalent with regard to environmental and chemical policy making in Europe. There are heated discussions between academics and

stakeholders on different sides of the policy aisle on chemical control policy issues such as endocrine disrupters where one group of scientists and stakeholders argue for a restrictive approach while another group disagrees (Autrup et al 2015; Vandenberg et al 2012; Zoeller et al 2014). Similarly, member states themselves are getting involved promoting their national “pet” regulation projects on the European level. Hence, we see Sweden, via its Ministry of the Environment as well as its Chemicals Agency, being highly active, either directly via promoting its vision for a toxic free society by 2020 within Europe (Lofstedt 2014a), or indirectly by funding the anti-chemical lobbying group the Chemical Secretariat based in Gothenburg to the tune of 5 million SEK per year (Swedish Chemicals Agency 2015). Similarly, the UK is pushing for a European acceptance of GMOs (Patterson 2014a and b; 2015) something which Germany and Austria are actively trying to oppose (Pollock and Shaffer 2009; Vogel 2012). Likewise, the UK is promoting a strong deregulatory stance through the publication of the October 2013 Business Taskforce report on deregulation (UK Department of Business Innovation and Skills [BIS] 2013).

Many of these efforts are driven by ideology rather than by evidence-based and risk informed policy making. The document, *Cut EU red tape: Report from the Business Task force*, published by UK BIS, and publically endorsed by the UK Prime Minister and raised both at a Cabinet meeting as well as at a European Summit, is rather ideological in scope and tone. The discussion surrounding endocrine disrupters and, in particular, the future use of Bisphenol A (BPA) in Europe is equally ideological. In this case the then Swedish Minister of the Environment, Lena Ek, sued the Commission over delaying the publication of the necessary criteria for banning different endocrine disrupting substances (EurActiv 2014) for political gain—she was hoping that it would help the Center party, which she represented at the time, to stay in power by promoting its green credentials at the expense of the Swedish Green Party (Lofstedt 2014b).

These efforts do nothing to promote evidence-based and risk informed policy making in Europe. They do not offer investors the predictability they need, nor do they lead to creative innovation, something that Europe is presently in short supply of. In addition, regulatory decisions based on ideology rather than science are difficult to enforce let alone implement. That said there are signs of scientific evidence being integrated more into EU policy making. The European Commission appears to be taking scientific evidence more seriously than before such as through establishing a Chief Scientific Advisor post to the then Commission President Barosso that remained in place between 2012-2014. This initiative was applauded by many observers as a substantial step forward in promoting evidence-based policy making in Europe (Girling 2014; Wilsdon

2014). Similarly, Julie Girling MEP was able to establish an informal working group on risk in the European Parliament in 2012 which was widely welcomed by policy makers and regulators (Lofstedt 2014b).

In the next section of this paper we summarize to date these two partial steps towards evidence-based policy making in Europe that took place in the period 2010-2014. In section 3 we examine where the new European Commission and Parliament are today one year into its mandate: is the Commission and Parliament taking evidence-based and risk informed policy making more seriously than before? In section 4 we highlight one policy issuer that continues to receive significant amount of adversarial policy attention namely the scientific and regulatory debate surrounding so called endocrine disruptors. In the final section of the paper we offer recommendations with regard to what the new European Commission and the new European Parliament should do next going forward. The paper itself is based on some 80 informal elite interviews with policy makers, regulators and stakeholders in Brussels, Dublin, Helsinki, London, and Stockholm, as well as by information gathered at past Informal Working Group of Risk meetings.

2. The Chief Scientist Post and the Informal Working Group on Risk

The EU Chief Scientific Advisor (CSA) post was created in late 2011 after suggestions from a number of member states. The idea of an EU CSA post was first suggested by Bruce Ballantine in a report for the European Policy Centre (Ballantine 2005). When Prof Anne Glover (the former Chief Scientist of Scotland) was appointed as the first EU CSA, the then President Barosso, released a job specification of what the CSA's role entailed noting among other things that Prof Glover should provide opinion and analysis of scientific issues that were of concern to the President and build strong relationships with other advisory groups and European agencies (such as EFSA and EMA) (for a detailed discussion see Alemanno 2014, p. 287-288). Glover's post was poorly resourced (at most her group was staffed with five full time equivalents) compared to the UK Government Science Office which has more than 50 FTEs so it remained unclear how much science the Commission actually wanted (Glover 2014). The mission of the EU CSA was not as clear as it could have been as some Commission civil servants felt that the CSA should be an adviser behind the scenes while others suggested that the individual should be in the spotlight (Alemanno 2014). In the end she did a bit of both advising Commission President Barosso internally (something that the NGOs in particular disagreed with) yet at the same time being an outspoken advocate externally for certain issues that she cared a great deal about such as GMOs (EurActiv 2013 and 2014). In 2013, for example Prof Glover noted:

“There is no evidence that GM technologies are any riskier than conventional breeding technologies and this has been confirmed by thousands of research projects.” (Glover in EurActiv 2013).

When she was in office she remained a strong promoter for evidence-based policy making. In February 2013 she established the President’s Science and Technology Advisory Council to provide the President of the Commission independent advice on a wide range of scientific and technology issues. In June 2014 she established a pan European network of government science advisors at the Euroscience Open Forum in Copenhagen.

By taking positions that were inherently unpopular among the wider NGO community such as being blatantly pro GMO and arguing for a rigorous evidence base regarding whether or not to ban endocrine disrupters she became quickly targeted by Greenpeace, Corporate Europe Observatory, PAN Europe and like-minded pressure groups. These groups started asking Anne Glover’s office for freedom of information requests and began to openly criticize her for providing advice to Commissioner President Barosso in secret (e.g. Alemanno 2014; Glover 2014). It should, therefore, not be seen as a surprise that in the middle of the summer 2014, a number of NGOs started lobbying the Commission President Elect Junker to scrap the CSA position arguing:

“The post of Chief Scientific Adviser is fundamentally problematic as it concentrates too much influence in one person, and undermines in-depth scientific research and assessments carried out by or for the Commission directorates in the course of policy elaboration.” (CEO 2014)

Following this initial letter there were a number of counter proposals arguing that the CSA position should remain. These letters came from industry groups, academic associations and advocacy bodies such as Sense about Science. A large number of these letters came from UK based organizations. After stepping down from her position (her mandate was only until the end of the Barroso Commission) Professor Glover has been highly critical of the pressure groups that brought her down, accusing Greenpeace for hypocrisy as it too has a Chief Scientist Post (Glover 2015a), as well as the Commission itself noting that incoming Commission President Junker decided not to meet her at all when he took office (Glover 2015b). In May 2015 the European Commission, under the lead of Commissioner Moedas, Commissioner for DG Research and Development, put forward a replacement strategy to the Chief Scientific Advisory post namely “A new mechanism for independent scientific advice in the European Commission”. This mechanism will be discussed in the recommendations section.

2.1 The Informal Working Group on Risk in the European Parliament

The idea of the Informal Working Group on Risk in the European Parliament came out of a Review that the first author did for the UK Government on health

and safety regulation (Lofstedt 2011; Lofstedt 2013). At the time of the publication of the Review the then Minister of Employment, Chris Grayling MP, and Ragnar Lofstedt launched the Review not only in London but also importantly in Brussels where at the time of the launch Julie Girling MEP decided to take on board this specific recommendation (Girling 2013). Upon the establishment of the Informal Working Group on Risk in September 2012 it met four times and discussed topics ranging from risk vs hazard to whether there was a need to revamp the Commission's communication on the precautionary principle (e.g. see Lofstedt 2014). The Group brought together regulators, policy makers, academics and NGOs for discussions ranging from round table lunches to all afternoon panel debates. The aim of the Group was not only to introduce, but more importantly, to discuss the importance of evidence-based and risk informed policy making in Europe. In addition, background papers were prepared for the meetings and these were used as vehicles to assist the European Commission and other actors to take policy action on certain risk related topics such as the future use of the substitution principle in Europe (Lofstedt 2014).

3. Where is the new European Commission and Parliament with regard to evidence-based and risk informed policy making?

As the new Commission has only been in power for less than a year at the time of writing and the Parliament a little longer than that, it is difficult to discuss underlying trends or directions. That said, there are some early "indications" regarding what these two bodies want to prioritize for their 5 year mandates and based on these indications one can note the following.

3.1 Transparency and the European regulatory agencies

In an era of increased public distrust toward policy makers in Europe and North America, partially caused by regulatory scandals such as BSE (see Lofstedt 2004 for a discussion), many regulators, pressure groups, journal editors and policy makers themselves have taken the view that greater transparency can rebuild trust in the regulatory and political processes (see Coglianese et al 2008; Coglianese 2009; Norris 2001; Pollitt and Bouckaert 2011). Transparency as a term is on the whole defined with little theoretical rigor (see Florini 1999), but it is understood by the public to mean honesty, independence and openness (Breakwell 2007; Schutz and Wiedemann 2000), and is seen as a critical tool to enhance legitimacy and promote accountability (Ball 2004; Meijer 2009). The pressure and demands to enhance transparency has been especially prominent with regard to European arm length agencies such as EFSA and EMA and this has continued to increase in the new Commission and Parliament (Way and Lofstedt 2015). For example, the then Commissioner for DG SANCO John Dalli noted at the time of the launch of the clinical trial register in 2011 that:

“The register launched today is good news for patients as it will allow them to get easier information about clinical trials going on in the EU, possibly giving access to important new treatment. It is also of great interest to healthcare professionals and carriers, the research community and industry.” (Dalli 2011)

Similarly, the present Executive Director of the European Medical Agency Guido Rasi noted:

“We live in an era where the public legitimacy demand transparent and openness of information to allow them to scrutinize the relationship between regulators and the regulated, so we will all need to adopt...the strategy of keeping data secret that should be open for public scrutiny to benefit public health has not worked. It is time for a different approach.” (Rasi 2013).

Going forward, these European agencies has promised even greater transparency. In October 2014 EMA launched it landmark clinical reports policy which called for all clinical reports that are submitted by pharmaceutical companies to be published online starting in January 2015 (EMA 2014). Likewise, in 2014, EFSA published its discussion paper “Transformation to an Open EFSA” which the Authority promises to improve the overall quality of available information and data used for EFSA’s outputs, as well as complying with normative and societal expectations including the “democratizing” of science such as by granting worried citizens access to raw data sets (EFSA 2014).

The transparency measures that EFSA and EMA are presently advocating are so called “fishbowl” type. Coined by Cary Coglianese (2009) fishbowl transparency can be described as “expanding the release of information that can document how government officials [including regulators] actually behave” (Coglianese 2009, p.xxx). For EFSA and EMA this has been done via data dumping such as releasing thousands of pages of periodic safety reports (PSURs) or raw clinical trials or scientific data that were deliberated on by scientific committees. Both agencies take the view that the more they release the better. Andreas Pott, the EMA’s Deputy Director stated in a letter to the Ombudsman that in 2014 the Agency had released 1816 documents containing 167,309 pages (Pott 2015). This is different from evidence or reason-based transparency policies in which regulators are asked to explain in a transparent fashion why certain scientific opinions and regulatory decisions were taken (e.g. why was a certain GMO substance approved for public consumption) (Coglianese 2009). The success of science-based transparency cannot be measured by some form of numeric value but rather whether publics or patients in question have received, digested and understood the information made available (Heald 2006).

3.2 Calls for better regulation

Better regulation is a topic that is a theme of fundamental importance for the new Commission. It is controlled by the First Vice President of the Commission Frans Timmermans who owns the better regulation portfolio. In the early days of the new Commission it was clear that better regulation would be a priority issue. As Timmermans spokesperson Natasha Bertaud noted in November 2014:

“The better regulation agenda is not just about optimizing future proposals but also about reviewing laws which no longer serve the purpose they were intended for, and then removing them from the statute books to remove any obstacles they create to growth and job creation. “
(Bertaud in EurActiv 2014).

The importance of better regulation for the new Commission was also shared by the Polish EU Commissioner for Growth Elzbieta Bienkowska when she argued in November 2014 that:

“We need to improve the investment environment by removing non-financial barriers in key industrial sectors...Investment in new manufacturing technologies in smart and clean industries will not happen if the regulatory framework at EU level is not conducive to growth.”
(Bienkowska in EurActiv 2014)

How the Commission wants to take its better regulation agenda going forward is spelled out in the May 2015 Communication on the topic (European Commission 2015). In the accompanying Press release Vice President Timmermans is quoted saying:

“This Commission is determined to change both what the Union does and how it does it. Better regulation is therefore one of our top priorities. We are listening to the concerns of citizens and businesses-especially SMEs-who worry that Brussels and its institutions don’t always deliver rules they can understand or apply. We want to restore their confidence in the EU’s ability to deliver high quality regulation. Better regulation is not about “more” or “less” EU rules, or undermining our high social and environmental standards, our health or our fundamental rights. Better regulation is about making sure we deliver on the ambitious policy goals we have set ourselves in the most efficient way.” (Timmermans 2015)

In other words, Timmermans sees the better regulation package including the Communication itself as a tool to help rebuild trust in the Commission through the carrying out of evidence-based and risk informed regulation, something that external observers have highlighted in the past (Renda 2006; Renda et al 2013).

In the Communication the Commission argues that:

“Better regulation is a tool to provide a basis for timely and sound policy decisions..” (European Commission 2015, p. 3)

Going forward the Commission in its Communication notes that it will listen more to the concerns of stakeholders and citizens by introducing 12 week long consultations for new proposals. In addition the Commission has decided for the first time to allow all stakeholders to provide detailed feedback on draft texts of delegated acts for a period of four weeks. The Commission realizes that it needs to better explain why it is enacting certain policies and what it hopes to achieve by doing so. Of especial importance here is to uncover whether the proposed regulation will have a negative impact on the competitiveness of small and medium sized enterprises (SMEs). The Commission calls for more transparency and to achieve this it established in December 2014 a Regulatory Scrutiny Board whose remit is to assess the quality of the regulatory impact assessments. Unlike the Impact Assessment Board that it replaces, the Regulatory Scrutiny Board will for the first time be composed of a chair person and six individuals who will work full time scrutinizing impact assessments. Of these six individuals, three of them will be recruited for a fixed term from outside the Commission. Finally, in this 2015 Communication the Commission urges rightly that the other European institutions should take more of an active role with producing impact assessments. For example, the Communication notes that in the period 2007-2014 the Commission produced more than 700 Impact Assessments, while the European Parliament produced approximately 20 and the European Council zero (European Commission 2015, p. 8).

It is unclear whether these and related changes will indeed lead to better regulations in Europe. For example, the much touted Regulatory Fitness and Performance Programme (REFIT) (European Commission 2012 and 2014) did not necessarily lead to more evidence-based and risk informed decisions as witnessed by the temporary ban of neonicotinoide pesticides (Alemano 2013) or the continued miss-use of the precautionary principle associated with, for example, endocrine disrupters (Lofstedt 2014) or the ongoing adversarial debate regarding GMOs (Freeman 2014).

3.3 The continued miss-use of the precautionary principle

In February 2000, the European Commission published a Communication on the precautionary principle (European Commission 2000). The aim of this Communication was to address credibility issues resulting from the Commission’s ad hoc, ill-defined and to a certain degree non-scientific application of the precautionary principle (Fisher 2007, 2010; Graham 2001, 2010; Wiener 2010; Zander 2010). On the whole the Communication was well received at the time by regulators, policy makers, academics and other actors

(e.g. Christoforou 2003). The Communication placed the precautionary principle within the existing framework of risk analysis arguing that:

“The precautionary principle should be considered within a structured approach to the analysis of risk which comprises three elements: risk assessment, risk management, risk communication. The precautionary principle is particularly relevant to the management of risk.” (European Commission 2000, p.3)

Initially the Communication was often cited in debates with regard to the precautionary principle. The Member States strongly supported the Communication and at the December 2000 European Council it was formally endorsed as a Resolution which:

“Called on the Commission to systematically apply its guidelines, making allowance for special features of the various areas in which they may be implemented , and to incorporate the precautionary principle, wherever necessary, in drawing up its legislative proposals.” (Christoforou 2003; p.242)

Commissioners themselves also promoted the Communication to its trading partners and other bodies. The Commissioner of the Environment at the time, Margot Wallstrom, noted in a key note speech in Washington DC:

“Our aim (of the Communication) was to promote transparency in light of public concerns stemming from the BSE and dioxin crises and to present broader understanding of the EU’s position on the topic. The Communication establishes guidelines for the application of the precautionary principle.” (Wallstrom 2002, p.3)

Over time, however, regulators and policy makers operating in the European space have moved away from applying the Communication (for an in-depth discussion see Lofstedt 2014). As a result the precautionary principle is consistently being misused, often together with hazard classifications rather than within some form of risk analysis framework (eg see Westerlund 2013). An example of that is seen in the ongoing discussions whether to ban or not to ban endocrine disruptors (discussed in section 4). The new Commission is aware of these problems (Lofstedt 2014) but have yet to decide what is needed to address them.

3.4 The continued pressure from member states to promote hazard classifications over risk analysis

It is clear from our own research interviews that Commission officials remain concerned that there is a lack of scientific consistency among member states when it comes to making regulations. Issues raised include why does Sweden take a difference stance on certain chemicals than the UK based on the same underlying scientific evidence (Zander 2010)? In addition why do some

countries and NGOs promote the complete ban of genetically modified organisms (ala Austria) while others are more in favour of it (such as Spain)? A great deal of the reasoning behind such decisions is politics: Sweden can promote the phase out of human made chemicals by the year 2020 as the country has a very small chemical industry and Austria can continue to argue for a GMO free zone around its national borders as it has no economic interests such as Monsanto promoting GM crops there. The nationalistic stance is, however, made problematic when these same nations try to promote their national vision on setting of European wide regulations using so called hazard classifications rather than risk based ones (Lofstedt 2011). One would have hoped that with the new Commission's interest in promoting better regulation would have resulted in more of a concerted effort by policy makers in the European Parliament and the European Council to promote risk informed policy making but this has not occurred. Rather member states continue to promote hazards based regulations within sectors that they are concerned about. Sweden, for example, continues to promote the use of hazard based chemical control policy within Europe (Lofstedt 2014a; Swedish Chemicals Agency 2015; Swedish Ministry of Environment 2013).

4. The never ending saga: The adversarial discussions on endocrine disrupters

Introduction

Bisphenol A (BPA) is a man-made chemical used in the manufacture of plastics developed in 1891. Because it increases heat resistance and durability, since 1957 BPA has been used to make a tough plastic (polycarbonate) to replace glass food containers (such as baby bottles), electronic products and car headlight assemblies (Vogel, 2009). Initially, BPA was also intended as a synthetic oestrogen hormone to help women with a range of issues, such as morning sickness (Alemanno, 2010).

Today, BPA is a hot political topic. Nearly everyone is exposed to it and concerns about exposure often focus on the most vulnerable population groups (such as infants). The controversy around BPA began in the early 1990s. It was noted that BPA could migrate from packaging used for consumer products and that the chemical- similar to other artificial and natural hormones- has the potential to be considered an endocrine disruptor, i.e. that it can act like hormones (Lofstedt, 2010).

A wide range of studies link BPA to adverse health effects in mammalian and non-mammalian laboratory, wildlife and in-vitro models (e.g. Nagel et al, 1997; Richter et al, 2007; Bonefeld-Jorgensen et al, 2007; vom Saal et al, 2007). Nagel et al's (1997) study on BPA indicated oestrogenic responses that were higher than anticipated. Vom Saal et al (2005) argued that their studies showed

that even very low levels of BPA can have significant health effects, including reproductive abnormalities, obesity, breast and prostate cancer and neurobiological problems (vom Saal et al, 2005).

However, these studies were criticized as unreliable by regulators both in the US and in Europe (EFSA, 2010), as not being reproducible (Gray et al, 2010), and as not reflecting real-world consumption (Butterworth, 2009). Further, expert panels from Harvard questioned the validity of vom Saal's findings, noting that they were inconsistent and raising doubts about any real functional or physical impairments caused by the BPA administered (Gray et al, 2004; Goodman et al, 2006).

The making of the controversy

Nevertheless, environmental groups took the view that vom Saal's findings were correct. Together with vom Saal's active media work this started to change the nature of the debate regarding BPA safety (Lofstedt, 2011). Endocrine disruptors were increasingly discussed in the US and Europe bringing the issue onto the political and public agendas (Lofstedt, 2010). Further momentum was gained through efforts by pressure groups many of them coming together as part of the Endocrine Society. The Endocrine Society (2009) issued a report expressing serious concerns about BPA, dioxins, PCBs, DDT and other endocrine-disrupting compounds, stating that there was strong evidence that endocrine disruptors could harm the reproductive system, cause malformations in fertility and various forms of cancer.

While the idea that drugs/chemicals could act like hormones has been around since decades, the advocacy groups of the 1990s drew public attention to the issues surrounding BPA. In terms of communication, advocates were very vocal and in a post-trust area the public are often more trusting in advocacy groups than in other agents such as government scientists (Lofstedt, 2005).

Yet still there are uncertainties in terms of how harmful BPA is exactly in humans. On the one hand, there has been increasing concern about the potential impact of BPA on human health (Rochester, 2013; Teegarden and Drury, 2013). Public concern was amplified by recent studies showing relationships between BPA exposure and obesity (Wang et al, 2012), cardiovascular disease (Melzer et al, 2010), behaviour (Braun et al, 2010), and birth outcomes (Lee et al, 2013). On the other hand, some analyses suggest no relationships between BPA exposure and adverse human health impacts (Lakind et al, 2012).

Regulatory responses

Whilst initially, the studies by vom Saal et al (2005) did not change the policy and regulation climate, responding to media and activists' pressure and

heightened public concern, regulators began to initiate more proactive rather than reactive risk communications (Lofstedt, 2011). By mid-2008 policy-makers started arguing for bans on BPA-containing plastics, despite EFSA (2008) concluding that it was safer than previously thought (EFSA 2008).

In October 2008, Health Canada decided to ban BPA from baby bottles, citing the need for precaution (Health Canada, 2008), a move strongly opposed by the chemical industry. By January 2010, nine US states had banned the use of BPA in baby bottles and 'sippy cups'. Even without concrete evidence that BPA was harmful to humans, industry began to stop producing BPA-containing bottles for the US market (Lofstedt, 2011).

This put pressure on other regulators and by 2010, the European Commissioner for Health and Consumer Safety overruled EFSA's (2010) scientific evidence and announced a ban on BPA in plastic baby bottles, citing fears that the compound could affect the development and immune response in young children. In the US, the FDA followed suit with a similar ban in 2012. But after reviewing 300 scientific studies (conducted between 2009-2013), the FDA found current exposure levels to be safe. Dennis Keefe (FDA) emphasized that: *"We make public health decisions based on a careful review of well performed studies, not based on claims or beliefs. We have to perform an unbiased evaluation of the data."*

Even with this information in 2013 US FDA regulations no longer authorize the use of BPA in infant formula packaging. According to the FDA, however, this was based on "abandonment" and not on safety (US FDA 2013).

A miss-use of the precautionary principle?

Lofstedt (2011) highlights that BPA regulations at local and state levels were increasingly based on perceived risk advocacy rather than on the most effective risk response, be it to food safety or public health- as defined by regulatory interpretation of existing data. The BPA case highlights an extreme application of the precautionary principle- not evidence-based but rather based on risk perceptions. Clearly, perceived risk differs from fact-based risk. In like manner, Prof Richard Sharpe (University of Edinburgh) argued that the ban was an overreaction and that the decision to ban was made on political, rather than scientific, grounds. Hence it is questionable whether the ban was a useful application of the precautionary principle.

In banning BPA, the EU acted with significant caution. Indeed according to the European Heads of Food agencies (HFA, 2012), the use of the precautionary principle by the European Commission (EC, 2010) actually was a misrepresentation of EFSA's opinion and had to do with media, stakeholder and member state pressures, rather than scientific evidence *per se*.

Substitution principle (risk-risk tradeoff)

Various NGOs, regulators and politicians welcomed this precautionary approach (e.g. Wemmert and Karlsson, 2013), and proposed replacing BPA with substitutes. However, this substitution brought with it a typical risk-risk tradeoff. It is not evident whether substitutes are worse or better than BPA. For example, BPS seems to have the same hormone mimicking effects as BPA. A joint report by the FAO and WHO showed the difficulty of substituting BPA-are the alternatives any safer (FAO/WHO 2010)?

Plastics containing BPA have been studied for decades and there is a degree of scientific certainty of how BPA reacts in these plastics. In contrast, substitutes for BPA have been far less researched and some of these may actually have a higher negative environmental or public health profile than BPA (Lofstedt, 2013). As such, there is the need to examine risk-risk tradeoffs, rather than simply applying the substitution principle (Lofstedt, 2013). It may not be possible to easily replace BPA as it is unclear whether the alternatives to BPA are indeed any better than BPA itself.

EU regulations: Lack of regulatory/scientific consistency between member states

EU member states lacked scientific consistency regarding the assessment and subsequent regulation of BPA. The potential harmfulness of BPA have been debated- with varying degrees of intensity- in many member states, most notably Sweden, Denmark and France.

In March 2011, a ban prohibiting the manufacture in the EU of baby bottles containing BPA came into force. This ban was extended in June 2011 to the import to the EU of baby bottles containing BPA. Alemanno (2011) argues that the science behind the ban was controversial as it reflected the challenges pertaining to the new toxicity testing. XXX Nevertheless, the industry voluntarily withdrew from the market baby bottles containing BPA and replaced them with supposedly safer products, capitalizing on the “BPA-free” label as a marketing tool.

In December 2012 the French Parliament adopted a law to suspend the manufacture, import, export and placing of the market of any packaging for food use containing BPA. France is the only country in the world to adopt such a precautionary stance towards all BPA-made food contact materials. ANSES’ (the French Agency for Food, Environmental and Occupational Health and Safety) assessment showed that under certain circumstances, the exposure of pregnant women to BPA could pose a potential risk for the unborn child. However, the confidence levels associated with these results were described as

moderate, highlighting the uncertainties in the state of scientific knowledge. Moreover, ANSES conducted a hazard rather than a risk assessment, i.e. showing that BPA can cause harm but not the likelihood of that occurrence.

Regulating a product in terms of hazard rather than risk is challenging and other EU member states disagreed with the French way of regulating. Several countries (e.g. Holland, Italy and the UK) lodged objections with the Commission, stating that this draft French law does not follow sound science and could become an unjustified international trade barrier (Alemanno, 2013). The industry organization PlasticsEurope lodged a complaint to the Commission, arguing that the French BPA law raises serious concerns both under EU and WTO law (Alemanno, 2013). The view was that France should not ban a product other member states and EFSA regard as safe, especially if based on a lower standard of scientific evidence.

EFSA and ANSES also disagreed on the quality and limitations of several of the epidemiological studies. EFSA argued that ANSES had not effectively demonstrated consumer risk and hence did not justify policy change on BPA, a conclusion also upheld in a WHO report (WHO 2012). Following on from these disagreements between member states, in 2013 EFSA launched a two-stage public consultation on its draft opinion on the possible risks from BPA. The first stage looked at EFSA's extensive assessment of consumer exposure of BPA in Europe, while the second stage looked at its assessment of the potential human health risks of BPA and recommendations that the current TDI can be lowered.

EFSA's new (2015) opinion

By January 2015, EFSA had conducted a comprehensive re-evaluation of BPA exposure and toxicity, weighing up a large body of new scientific evidence. EFSA utilized new methodologies to take into account uncertainties regarding potential health effects, exposure estimates and human health risks. Findings showed that very high doses of BPA are likely to have adverse effects on kidney and liver function (at least in animals) but people are not exposed to these levels. BPA may- but is unlikely- cause other health effects, such as on the reproductive, immune and nervous systems. As those could not be excluded, they add to the overall uncertainty about BPA-related hazards and were included in EFSA's assessment (EFSA, 2015).

In 2006, when EFSA last assessed dietary exposure to BPA, less data was available and EFSA's experts were required to make conservative assumptions about consumption as well as the levels of BPA in food. With more and better data subsequently in place, EFSA updated and more accurately estimated the

risks. For instance, it was shown that dietary exposure is four to fifteen times lower than previously estimated, depending on the age group (EFSA, 2015).

EFSA concluded that at the current levels BPA does not pose a risk to human health (including risks to unborn children and infants) as the quantities absorbed by consumers are significantly below what would constitute a risk. Even when adapted to the new, lower TDI levels there is no health risk from BPA exposure (EFSA, 2015). EFSA was as open and transparent as possible, consulting and engaging with national stakeholders and authorities during the risk assessment process so that the widest range of scientific views and information could be considered (EFSA, 2015). In terms of risk communication with the public, EFSA prepared a lay summary of its scientific findings. Further, EFSA also committed to reconsider the temporary TDI in lights of the findings of the US National Toxicology Program, which are expected in two to three years.

Industry welcomed EFSA's new assessment. Jasmin Bird (PlasticsEurope) proposed: *"This EFSA conclusion on BPA should be used as a basis for consistent and harmonized European food safety regulation, and should be respected by all member states."* (Euractiv, Jan 2015).

The British Coatings Federation (BCF) asked the Commission to challenge the French ban on BPA following EFSA's new opinion backing the chemical, arguing that the ban is distorting and creates different standards for France vs. the other member states (Industry News, Feb 2015). Tom Bowtell (CEO of BCF) highlighted that *"BPA has become a political hot debate, science has gone out of the window..."* (Industry News, Feb 2015).

This debate is certainly set to continue. In March 2015 both DG Industry and DG Sante opened infringement procedures against France. In September 2015 the French Constitutional Council overturned a ban on BPA in export products.

Conclusions

The risk assessment of BPA has been controversially debated for years. BPA still is an *"emotionally heated topic"* (Lofstedt, 2013, p.16). A risk assessment approach needs to consider both potential adverse effects of endocrine active substances together with their likelihood of exposure (EFSA, 2013). These findings can then best inform the decisions of EU risk managers to protect consumers and the environment from risks associated with endocrine disruptors in the food chain. However, to date many advocates have favoured a hazard- rather than a risk-based assessment. The BPA case emphasizes the need for an EU harmonized definition of the term "endocrine-disrupting chemical" based on the endocrine activity displaying clear adverse events.

The BPA case highlights the pressure that exists today to move away from regulation based on scientific risk assessment *per se* to regulation based on the perception of risk. Pressure groups and key advocates argued for policy changes without the necessary science required supporting these changes (Lofstedt, 2011). As such, the public controversy surrounding BPA influenced the regulatory decisions. At least temporarily, this was done at the expense of scientific evidence. The BPA issue underlines the challenges when scientific and regulatory controversies come together. It shows the need for more science-based regulations and evidence-based policy-making. Lofstedt (2011) stresses the importance of establishing more independent risk communication advisory boards so that debates can focus on expert risk assessments and become less politicized. Public awareness of BPA risk is essential but it is vital that information allows consumers to discriminate between real and perceived risks (Teegarden and Drury, 2013).

It is important to get risk assessment right. BPA remains a controversial and adversarial topic with a seemingly varied future between EU member states. In many respects, BPA can be seen as a ‘test case’ in the public’s concerns about household chemicals, pollution and the links between illness and exposures. While to date it should be seen as the most well-known potential to be considered an endocrine disrupter to capture the public’s attention it is not the only one.

5. Recommendations for the new Commission and Parliament

Over the next 5 years, there are a number of recommendations that the Commission could implement in order to promote evidence-based and risk-informed policy making. This is especially vital for the Commission to pursue if it is to be successful in negotiating a free trade agreement with the United States under TTIP. It is also important to ensure that EU Regulations and Directives more generally are fair, consistent, predictable and evidence based, all crucial variables if we are serious in promoting a more innovative Europe. So what could the European Commission do? There are a number of key recommendations that are worth pursuing.

5.1 Making the Commission’s new mechanism for independent scientific advice work

Following the decision by the Commission President Junker to axe the Chief Scientific Advisory position, there was genuine concern among regulators and policy makers in the UK that the new Commission would not make decisions based on evidence or even worse be anti-science (Economist 2014; Wall Street Journal 2014). Therefore Sir Paul Nurse, the President of the UK Royal Society, and other senior academics welcomed the Commission’s new proposal

for a new mechanism for independent scientific advice in May 2015 (European Commission 2015). The aim of this mechanism is to show that the Commission takes independent scientific advice seriously. For the mechanism to work, however, the high level group of eminent scientists who are independent and who have now been appointed that they are properly resourced.. Secondly, the operational support unit working for the eminent scientists need to actively engage with the wider scientific community and the European/National Academies of Sciences to ensure that the advice it receives is based on highest level of evidence. Ideally this should be done in a proactive manner. Finally, the scientific advice coming out of this process must be communicated to the affected DGs as early as possible so the advice provided can have a real policy impact.

5.2 Move away from fish bowl transparency to science based transparency

There is a need for science based regulators such as EFSA or EMA to move away from fish bowl transparency and move to science based transparency, where some specific data is shared but at the same time explained (Bouder et al 2015). The push for dumping data on line, putting clinical trials into the public domain, recording scientific debates as well as arguing for ever stricter conflict of interest statements do not lead to more trusted regulatory agencies or better policy making (Bouder et al 2015; Way and Lofstedt 2015). Rather what we see is that the information from these activities that are put out in the public domain is used as ammunition by the groups attacking the Agency in the first place in order to reduce the credibility of the Agency in question (e.g. CEO 2013; 14 and 15; Robinson 2013).

Similarly, while we have found that although public and patients would welcome raw and uncertain scientific data entering the public domain, they would, however, become concerned, worried and/or confused about what the complicated data actually means with many saying that they would stop taking their medicines were it published online on a public website (Bouder et al 2015; Lofstedt and Bouder 2013; Lofstedt and Way 2014a and b). Finally, there is a need to remember that data dumping is not science communication.

5.3 Moving toward a more evidence based use of the precautionary principle

As noted in section 3.3 the precautionary principle is increasingly being misused. It is as if the Communication on the principle never happened. This has frustrated some observers. As Marchant et al argue:

“The evidence summarized...has demonstrated that the precautionary principle holds back technology, innovation, incomes, environmental improvements, and health benefits, while increasing trade disruptions,

risks and human suffering. The precautionary principle is a tried but has failed as a risk management strategy. It is time to move beyond it.”
(Marchant et al 2013, p. 16)

This is unrealistic. The precautionary principle is in the Maastricht treaty and one can therefore simply not remove it. Rather regulators and policy makers need to work with the various European institutions to ensure that the future use of the precautionary principle is evidence-based and risk-informed. In addition, what is needed now is for the Commission once again to provide a clear and concise definition of the precautionary principle that could be done by reiterating and possibly updating the Communication from 2000 (see Lofstedt 2014).

5.4 Strengthening the capacity of the European Commission to further promote evidence-based and risk-informed policy making

From discussions with officials in the European Commission it is clear that there is a need to further strengthen the capacity of promoting evidence based and risk informed policy making. Going forward what is needed is for the Commission to firstly, hire more in-house expertise so as to be less dependent on outside consultants. The Commission is unable to retain a long term memory of decisions taken on past risk related issues as elements of the decision-making process have in many cases been outsourced.

Secondly, there is a need for the Commission to spend more funds on evaluating past regulatory decisions and setting up an evaluation culture within the Commission itself (e.g. see Dunlop and Radaelli 2015; European Commission 2007; 2013; Smismans 2015). Commission officials have noted that there is a strong link between an evaluation culture and policy learning. To ensure adequate learning, however, the evaluation work should also be done in-house. At present time some 80% of the Commission’s evaluation work is outsourced (Smismans 2015).

Thirdly, the Commission is often accused for making decisions that are not firmly grounded on science (Patterson 2014 and 2015). To address this criticism going forward, the Commission should as a matter of principle provide detailed feedback if it decides to disregard scientific opinion.

5.5 Member states need to be more receptive to science based policy making

As has been seen in the above, many member states push their national pet risk projects in Brussels. Sweden and Denmark attempt to persuade European Parliamentarians to take a stronger anti chemical line and argue for the banning of more chemicals while Austrians and to a certain degree Germany push for strong anti GMO legislation—with Austria declaring that it wants to be a GMO

free zone. These national pet risk interests are making it hard for the European Commission to promote evidence-based policy making in Brussels. It is difficult, for example, for a Commission official working on REACH related issues to have an evidence-based discussion with a representative from the Swedish Chemicals Agency who wants to phase out all human made chemicals by the year 2020. Going forward there is a need for member state representatives themselves either via the European Council or certain Parliamentarians to take an active interest to move away from ideological positions to more evidence-based ones. One way of doing so would be to show the wider European consequences for a nation like Sweden demanding for a phase out of all human made chemicals (for a broader discussion see Lofstedt 2015).

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